

EXHIBIT 26

LETTERS TO THE EDITOR**Academic Radiology, Vol 11, No 12, December 2004**

improvement; if used alone, however, it will lead to under-reading, for several statistical reasons. The substantial differences among the expert panel for positive films in the article by Gitlin and colleagues illustrate one aspect of the problem. Requiring positive agreement among multiple readers is no more logical than the same requirement for negative agreement: without additional quality assurance, such a step would be insufficient and punitive. If the goal is to standardize readings, several approaches could improve quality assurance. Ultimately, all of these approaches amount to a concerted effort to reduce the number of readers to a group that will read similarly. An "asbestos board," with experts who undergo ongoing quality assurance testing and are also retained for continued normative behavior and dropped for non-normative behavior, is probably the simplest approach (4). There is no "gold standard," but we can achieve consistency. The barriers are political, not statistical.

Because the mixed messages from certified interpreters affect our patients' health beliefs, and because health beliefs affect behavior at many levels, the data presented are sufficient justification for considering the current system. The goal is not to choose a winning side—taking sides is part of what has gotten us to where we are today. Rather, the goal is to provide quality assurance. Some means to ensure consistent behavior, most likely in a small number of readers who undergo continual, random, voluntary quality assurance testing processes, is the socially useful solution. Getting there will require a "C-reading" from a planning committee that demonstrates competence, compassion, courage, and compromise.

Author's disclosure

Dr. Ducatman is not a B-reader and does not receive personal payment for testifying concerning his patients. Dr. Ducatman is an internist and occupational physician, and some of his patients are seen for reasons related to asbestos exposure. He has been queried, by either plaintiffs' or defense attorneys, concerning clinical findings and epidemiologic aspects of asbestos exposure, including quality assurance.

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From:

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To the Editor:

The stated purpose of the article by Gitlin et al (1) on comparing B readers' interpretations of chest radiographs for asbestos-related changes was "to determine if chest radiographic interpretations by physicians retained by attorneys representing persons alleging respiratory changes from occupational exposure to asbestos would be confirmed by independent consultant readers." This is an important objective scientifically and for public policy, and has major legal ramifications. However, because of potential flaws in the design, execution, and analyses of Gitlin and colleagues' study, that were ambiguously reported in their article, the study objective may not have been achieved.

An essential element in the design of this type of study is the process by which films are selected for inclusion in the study. In order for the results to be interpretable and generalizable, films entered into the study must be randomly selected and therefore likely to be representative of the distribution of all similar films, and thus free of bias. In the article by Gitlin et al., the film selection process is described as follows: "Seven groups of films and initial reports, totaling 551 cases, were made available to the authors from several legal sources. The authors were not given the names of the plaintiffs' law firms nor was demographic material provided about the individuals who were examined."

Gitlin and colleagues' article carries no description of the film-selection process used in their study, and it would appear that the authors have no knowledge of this process, since they did not select the films. We are not

told whether films were selected randomly. We are not told whether the 551 cases used in the study are a sample that is representative of all cases in the "universe" of plaintiff films submitted for litigation purposes. On the basis of the text of the article, it would appear that the authors could not address these issues. In fact, the article implies that the films were selected by defense law firms that have an interest in rebutting the film interpretations of the B readers hired by plaintiffs' counsel. In other words, the films may have been selected by parties that stood to benefit by biasing the outcome of the study. Hence, it is possible, if not likely, that the films included in this study were selected because they represent the worst examples of bad readings by plaintiffs' B readers. If the selection of films were to have been done for this reason, the proportion of diagnoses not supported by re-reading would be overestimated.

The criteria and process for selection of the 7 consultant B readers are not described. The problem in relation to selection of the consultant readers is similar to the problem outlined above for film selection. Who selected the consultant B readers? Were they selected by the authors, or were they selected by the defense law firms that funded the study? Were the consultant B readers a representative sample of all B readers, or of all B readers that provide service to defense law firms? While there may be biased B readers hired by plaintiffs' lawyers, the same problems with bias may theoretically occur with B readers hired by defense lawyers. Biased selection of the consultant B readers could lead to bias in the results of the study. Without knowledge of the criteria and process used for selection of the consultant B readers, the results of the study suffer from unknown bias, and are not interpretable.

The stated objective of the study is one-sided, since the study sought only to assess the validity and potential bias of B readers hired by plaintiffs' lawyers. The research question should be posed in a symmetric manner: Are B readers used in the context of asbestos litigation biased, and are B readings performed in this context biased? This would apply to B readers hired by plaintiffs' lawyers and B readers hired by defense lawyers. Because the study examines only one half of the question, readers of the study may mistakenly assume that B readers hired by defense lawyers are inherently more objective and less biased than B readers hired by plaintiffs' lawyers. Although there are reputable B readers who provide service to defense and/or plaintiffs' lawyers, there is no scientific foundation for the assumption that one set of B readers is

more or less biased than the other—no published studies specifically examine the validity or biases of B readers hired by defense lawyers as compared to B readers hired by plaintiffs' lawyers.

The last paragraph of Gitlin and colleagues' article, immediately before the concluding section of the article, states the following:

"In addition to the present study, the authors reviewed the world literature on chest X-ray studies of lung changes related to mineral dust retention in various worker populations (22–37). These reports discussed studies in several countries of worker populations exposed to asbestos and other mineral dusts. Most of the studies used the ILO 80 system as a means of recording their findings. Allowing for variations in technique, the studies cited involved interpretation of radiographs by more than one expert reader with aggregate results reported. In no instance did the conclusions agree with the high level of positivity (1/0 or higher on the ILO scale for small opacities) reported by the initial readers in the current study. The proportion of parenchymal abnormality—small opacity profusion ratings of 1/0 and higher—reported by the initial readers were significantly higher than those recorded by the consultant readers. The findings in the literature, which apply to asbestos worker groups and those exposed to other mineral dusts, support the results of the consultants' interpretations in this study rather than the high levels of positivity reported by the initial readers."

The conclusion stated here is without foundation, and fails to account for selection of cases that occurs in the context of litigation. While in any given worker cohort the prevalence of radiographic abnormalities may be high, medium, or low, one would anticipate that only those workers believed to have radiographic abnormalities would file claims for compensation. Hence, the prevalence of radiographic abnormalities among persons who file claims would be expected to be at or near 100%, regardless of the prevalence of such abnormalities in the larger population from which these persons were drawn.

We share the concern of Gitlin and colleagues that various biases may occur with B reading in the context of asbestos litigation. However, in the study they conducted, neither the process for selecting films nor that for selecting consultant B readers was defined, and both may have suffered from unknown selection biases. For these reasons, and without further information, no valid scientific conclusions can be drawn from Gitlin and colleagues' investigation.

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Dr. Franzblau receives consultant fees from both defense attorneys and clients and from plaintiffs' attorneys and clients in the context of asbestos litigation. Dr. Gillespie does not receive any consultant fees related to asbestos litigation.

REFERENCE

1. Gitlin JN, Cook LL, Linton OW, and Garrett-Mayer E. Comparison of readers' interpretations of chest radiographs for asbestos related changes. *Acad Radiol* 2004; 11(8):843-856.

RESPONSE TO LETTERS ON B-READERS STUDY**From:**

Joseph N. Gitlin, DPH
 Leroy L. Cook, BA
 Otha W. Linton, MSJ
 Elizabeth Garrett-Mayer, PhD

It was no surprise that the August publication of our article "Comparison of 'B' readers' interpretations of chest radiographs for asbestos-related changes" in this journal (1) stirred controversy and a backlash from some who have a vested interest in asbestos compensation litigation. The study described in our paper was a "real life" comparison of available chest-radiograph readings and not a random sample of a definable universe. We were careful to restrict any extrapolations from our data and to explain the methodology used in the study and its limits. We focused on the comparison between actual readings by plaintiffs' experts (initial readers) and our blinded expert panel of B readers (consultants).

Questions about our methodology have been raised by Rosenman; by Franzblau and Gillespie; and by Oliver, Harbut, and Welch, and we address those. Some of what we note here is in our article, but some details were omitted because of space restrictions.

We were asked whether sponsorship by defense attorneys of the analysis on which our paper was based created an inherent bias. Would a survey sponsored by plaintiffs be biased? In either instance, the answer would depend upon the success of efforts to avoid bias. By blinding our readers to the provenance of the films they read and to the source of the readers' compensation, we believe we achieved that goal. The political climate of asbestos litigation is such that no one, scientist or otherwise, would not be accused of bias by those who disagree.

In responding to the questions raised in the correspondence regarding our article, we make the following points:

- As stated in our paper, the basic research and expert readings were paid for by defense law firms. The selected B readers were engaged and paid directly by us and were blinded to the source of their payments. The readers also were blinded to the source of the chest radiographs they read, to the identity of law firms on either side, to the status of the films in litigation, to the identity of previous readers, to the identity of the individuals represented by the films, and to the results of their individual and cumulative efforts. They now know what was contained in our published paper.
- The consultants' interpretations produced 6 sets of readings involving 7 readers. One consultant was unable to continue after reading 295 cases, and his successor read 197 further cases. We chose all of the readers from our acquaintances and inquiries, to obtain experts whose competence and probity were known. The readers included 5 radiologists and 2 pulmonologists, all with significant academic credentials and extensive bibliographies on chest imaging and occupational respiratory diseases. Some are members of the International Labour Office (ILO) chest radiology panel. Some are members of the American College of Radiology Task Force on Pneumoconiosis. Some have been readers for the National Institute for Occupational Safety and Health (NIOSH) in various trials. One had consulted primarily for plaintiffs, 2 consulted for both plaintiffs and defendants, 2 consulted primarily for defendants, and 2 had no previous participation in reading films for litigation.
- Questions are raised about the range of positive readings reported by our experts. We argue that this range is a strength. Our deck was not stacked. Rosenman suggests that we should have eliminated outliers. Given the nature of our study and the small number of readers both in the initial group and among the consultants, we believe that defining outliers would have been an inappropriate decision, eliminating an unacceptably large number of cases in our data base. Paragraph 8, below, also addresses this issue.
- All of the films used in this study originally came from plaintiffs' counsel. Under legal rules of dis-